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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|---------------------------|---------------------|------------------|
| 10/509,139  | 09/27/2004  | Reddy Bandi Parthasaradhi | H1089/20010         | 1949             |
| 3000  | 7590        | 05/07/2009                | EXAMINER            |                  |
| CAESAR, RIVISE, BERNSTEIN,<br>COHEN & POKOTILOW, LTD.<br>11TH FLOOR, SEVEN PENN CENTER<br>1635 MARKET STREET<br>PHILADELPHIA, PA 19103-2212 |             |                           |                     | CHANG, CELIA C   |
| ART UNIT  |             | PAPER NUMBER              |                     |                  |
| 1625  |             |                           |                     |                  |
|   |             |                           | NOTIFICATION DATE   | DELIVERY MODE    |
|   |             |                           | 05/07/2009          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

|                              |                        |                      |  |
|------------------------------|------------------------|----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>  |  |
|                              | 10/509,139             | PARTHASARADHI ET AL. |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>      |  |
|                              | Celia Chang            | 1625                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 12 February 2009.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-14 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/12/09.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

1. Amendment and response filed by applicants dated Feb. 12, 2009 have been entered and considered carefully.

Claims 15-16 have been canceled. Claims 1-14 are pending.

2. The rejection of claims 1-2 under 35 USC 102(b) is maintained for reason of record.

The prior art disclosed a crystalline(+)citalopram (see RN 219861-08-2) prepared from crystallized from acetone. The instant claimed (s)-citalopram oxalate was prepared in the same manner using acetone as the solvent. Since a product cannot be separated from its physical property, therefore, the limitation of claims 1-2 are innate nature and inherent anticipation was found.

Applicants argued that in the original claims, solvent including acetone has been deleted. Such argument does not offer any evidence that the instant material is a "different material" which is prepared by non-acetone solvent or any factual evidence that the acetone crystallized material of the instant examples 1, 2 or 5 are *different* from the prior art since identical process was employed.

3. The rejection of claims 1-2 and 3-7 under 35 USC 112 first paragraph is maintained for reason of record.

Were applicants argued that claims 1-2 is a different material prepared from non-acetone solvent then, the new matter rejection is still applicable. Please note that the only Form I prepared in examples 1, 2 and 5 are from acetone. The exclusive disclosure of acetone as the sole solvent for preparing form I (S)-citalopram oxalate is tantamount to a teaching away from using any other solvent absent of factual support.

In view of the exclusive operability limiting to making form I using acetone only, a 112 first paragraph rejection of enablement is maintained for reason of record absent of factual support. It self contradictory to argue that the product is different from those made from acetone since none of the form I made in the specification support such an argument. The exclusive

disclosure of acetone as the sole solvent for preparing form I (S)-citalopram oxalate is tantamount to a teaching away from using any other solvent absent of factual support.

**4.** The rejection of claims 8-9 under 35 USC 102(e) or alternatively under 35 USC as being new matter is maintained for reason of record.

Were applicants argued that claims 8-9 prepared from methanol or isopropanol is a different material than the ones prepared from ethanol, the new matter rejection is still applicable. If the claims are drawn to material made by alcoholic solvents including ethanol as described in the specification, then the 102(e) rejection is applicable because application disclosed material made using methanol/isopropanol which was disclosed being the same as those made from all other alcohols.

**5.** The rejection of claims 10-11, 13-14 under 35 USC 112 first paragraph is maintained for reason of record.

Please note that no where in the specification have provided evidence that methanol alone without anti-solvent diisopropyl ether will give the form II. The exclusive disclosure of methanol/diisopropylether and isopropanol in a field of extreme high degree of experimentation is tantamount to a teaching away from using any other solvent absent of factual support.

**6.** The rejection of claims 1-7 under 35 USC 103(a) over US 4,943,590 in view of Cheronis supplemented with Sanches '613, '011 or '686 or claims 8-14 under 35 USC 103(a) over US6,916,914 in view of Cheronis supplemented with Sanches '613, '011 or '686, are maintained for reason of record.

The gist of applicants argument is that one would not employ different solvent with expectation to obtain the same crystalline form because of the high degree of unpredictability of the art. This is self contradictory, please note that if applicants argued that form I as now being claims are made by ethyl acetate, methyl t-butyl ether and acetonitrile which is different from the material made by acetone; then, none of the material made by examples 1, 2, or 5 is the claimed material and nowhere in the specification provided antecedent basis or operability of what that is. However, if applicants argued that changing solvent from acetone to ethyl acetate, methyl t-butyl

ether and acetonitrile will produce the same product, then, the 103(a) rejection is proper since prior art disclosed operability of generic solvents (see p.11 previous office action). The same is true for that if applicants argued that form II as now being claims are made by methanol/isopropanol which is different from the material made by ethanol; then, the none of the material made by methanol without antisolvent is the claimed material and nowhere in the specification provided antecedent basis or operability of what that is. However, if applicants argued that changing solvent from methanol/isopropanol to other alcohol will produce the same product, then, the 103(a) rejection is proper since prior art disclosed operability of generic solvents (see p.11 previous office action).

The post application pregrant application as recited in the previous office action, although are published after the filing date but provided factual support *consistent* with the teaching of Cheronis supplemented with Sanches and flows naturally with the teaching of the prior art. Therefore, the posted references are mere evidencial support for the obvious conclusion as delineated in the previous office action based on prior art.

**7. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**8.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*May 4, 2009*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*